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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/648,270	05/15/96	TOR Y	A-63463-1

HM22/0126

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EXAMINER	
CRANE, L	
ART UNIT	**PAPER NUMBER**
1623	32

DATE MAILED: 01/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/648,270	Tor et al.
Examiner	**Group Art Unit**
L. E.Crane	1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ------3--MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

XX Responsive to communication(s) filed on 01/05/01 (Amdt G)----------.

XX This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

XX Claim(s) 44-49 ---------- is/are pending in the application.

Of the above claim(s)---------- is/are withdrawn from consideration.

☐ Claim(s)---------- is/are allowed.

XX Claim(s) 44-49 -X---------- is/are rejected.

☐ Claim(s)---------- is/are objected to.

☐ Claim(s)---------- are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on---------- is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on---------- is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)----------.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:----------.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).---------- ☐ Interview Summary, PTO-413

XX Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other----------

Office Action Summary

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

Review of all of the amendments submitted indicates that while prosecution assumes that claims 1-43 have been canceled, claims 15-16 have not actually been canceled by applicant. Applicant is respectfully requested to indicate on the record the status of claims 15-16. The instant Office action, like applicant's response of January 5, 2001, assumes that all of claims 1-43 have been canceled.

No claims have been canceled, claims 44-46 and 48 have been amended, and no new claims have been added as per the preliminary amendment filed January 5, 2001.

Claims 44-49 remain in the case.

The disclosure is objected to because of the following informalities: in claim 48, line 6, the term "isselected" is a misspelling of
-- is selected --. Also, in claims 46 and 47 the "nucleic acid moiety" is defined in claim 47 to "comprise[s] [a] nucleic acid analog" is technically incorrect because the former is properly a substituent and the latter is a compound.

Appropriate correction is required.

Claims 44-49 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in

the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 44-49 the subject matter is directed to a vast array of substituent moieties but applicant's disclosure is limited in its specific embodiments to substituted nucleosides, substituted nucleotides, and substituted nucleoside phosphoramidites and nucleic acid sequences including a substituted nucleoside. For example, in claim 44, line 5, the term "M is a transition metal ion" is lacking in enabling support within the instant disclosure in the form of any showing that applicant had possession of compounds of the kind indicated, that a substantial number of transition metal complexes had actually been made, and that the method of making described in sufficient detail to permit the ordinary practitioner to know how to make said compounds based on contents of the instant disclosure. Previous policy guidance on enablement to the effect that the "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves" {*In re Gardner et al.*, 166 USPQ 138 (CCPA 1970)}, has apparently become the judicial policy of the successor (CAFC) court. Examiner refers applicant to the recent April, 1999 ABA meeting in Washington, DC and the Program Book therefrom wherein numerous appellate practitioners reported that claims lacking proper enabling support were being dispatched by that court to the circular file via findings of invalidity, a policy which the practitioners promised is in the process of being extended by the CAFC to all subject matter areas. Therefore, examiner respectfully suggests that the instant claims be redrafted with this policy in mind, and that additional data if

available be added in CIP filings as appropriate to support claims drafted to include presently non-enabled subject matter.

Applicant's arguments filed January 5, 2001 have been fully considered but they are not persuasive.

Applicant's submission of a reference (PTO-892 ref. X) wherein one of the named applicant is a co-author suggests that applicants may think that such a disclosure in the literature justifies the grant of a patent. However, examiner respectfully disagrees. As noted in *Brenner v. Manson* (148 USPQ 689; S. Ct. 1966) a patent is granted for results already in hand and is "... not a hunting license." However, such published results may be incorporated into a new or CIP patent application and would then provide a basis for overcoming the instant grounds of rejection. Applicant is reminded that it is well known and established that "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves." *In re Gardner et al.,* 166 USPQ 138 (CCPA 1970).

Applicant's response of January 5, 2001 at pages 4-5 argues that only prospective disclosure is required. Examiner respectfully disagrees noting both *Brenner v. Manson* and *Gardner* noted above and also noting that the statute cited requires an adequately enabled disclosure. Applicant is making new chemical compounds without meeting one of the key requirement of the bargain represented by the patent grant; namely that applicant provides a confidential but complete disclosure of how to practice the invention prior to and in return for the grant, applicant permits publication of the disclosure, which following expiration of the patent grant becomes part of the public domain.

Claims 44-49 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 44-49 are broadly descriptive of the claimed invention, but the specific embodiments teach with a very small number of example how the instant invention may be carried out, but no examples which disclose how to incorporate the instant claimed compounds into an oligonucleotide. Additionally, there are no examples which disclose how to make any of the requisite intermediate nucleoside and nucleotide-precursor compounds numbered "9," "10," "11" and "12" in the disclosure at pp. 12-13. For these reasons the exemplifications included within instant claims 44-49 are deemed to represent subject matter which would require undue experimentation by the ordinary practitioner to determine how to make said compounds, and that therefore said claims lack adequate enabling support within the instant disclosure.

Applicant's arguments filed January 5, 2001 have been fully considered but they are not persuasive.

Applicant is directed to the comments following the previous rejection.

This is a CPA of applicant's earlier Application No. 08/648,270. All remaining claims are drawn to the same invention claimed in the earlier application and could have been finally rejected in the next Office action if they had been entered in the earlier application. Accordingly, applicant's amendment necessitated the new grounds of

rejection. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action in this case. See t 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. §1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines now operated by Group 1600 are (703) 308-4556 and (703) 305-3592 for Official documents. Before transmission of any Draft communications, Applicant is respectfully requested to seek instructions from instant Examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec
01/24/01

GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600